

**Remarks/Arguments:**

Claims 11 and 19, amended hereby, are pending.

Claims 1-10, 12-18, and 20-22 are canceled, without prejudice or disclaimer.

Claim 11 is currently amended by incorporating claim 15; in other words, claim 11(amended) corresponds to claim 15, rewritten as an independent claim. Claim 11 is further amended in order to more clearly define the invention, i.e., clarifying that the "promoter" (in line 2) is a "T7 promoter," and by clarifying that one of the recited alternatives limiting "the transcribed RNA is . . . an RNA having the same sequence as the target RNA." Claim 19 is amended by incorporating claim 20; in other words, claim 19 (amended) corresponds to claim 20, rewritten as an independent claim.

Claims 11-22 were rejected under 35 USC 112, 2<sup>nd</sup> ¶, as allegedly being indefinite. Reconsideration is requested in view of the changes to claim language, and the cancellation of claims, effected by the instant amendment.

In analyzing the claims for compliance with §112, ¶2, it must be borne in mind that requiring some thought to understand the meaning of the claims does not render the claims indefinite under §112, ¶2. *S3 Inc. v. nVIDIA Corp.*, 59 USPQ2d 1745 (Fed. Cir. 2001).

The purpose of the claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not "indefinite" simply because it is hard to understand when viewed without benefit of the specification.

59 USPQ2d at 1748. While claims are to be given their broadest reasonable interpretation during prosecution, the definition of a claim limitation given by the PTO cannot be different than would be given by one of ordinary skill in the art. *In re Cortright*, 49 USPQ2d 1464 (Fed. Cir. 1999).

According to the statement of rejection, an allegedly confusing limitation found in claims 11 and 21 was the sole basis for the rejection. The limitation at issue reads "wherein the transcribed RNA is the target RNA." With respect to claim 21 (and claim 22, dependent thereon), the rejection is rendered moot by cancellation of claim 21 (and claim 22), hereby. The rejection is also rendered moot as applied against claims 12-18, since these claims are also cancelled, hereby.

With respect to claim 11, the claim is hereby rewritten to recite "wherein the transcribed RNA is . . . an RNA having the same sequence as the target RNA." Applicants submit that the instant amendment resolves any ambiguity perceived with respect to the limitation at issue, keeping in mind that requiring some thought to understand the limitation at issue, as currently amended, does not render claim 11 (amended) indefinite. *S3 Inc.*, 59 USPQ2d at 1748. Accordingly, withdrawal of the rejection under §112, ¶2, appears to be in order.

Claims 11, 12, 17, and 18 were rejected under 35 USC 103(a) as allegedly being unpatentable based on *Nucleic Acids Research*, 26, 1854-1855, 1998 (Nakahara) in view of US5654142 (Kievits). The rejection is rendered moot by the instant amendment, which effectively cancels the rejected claims. That is, rejected claims 12, 17, and 18 are cancelled, outright, and claim 11, as amended, corresponds to claim 15 (rewritten as an independent claim), which was not included in the rejection—and, as such, was found implicitly patentable over the cited references (as pointed out in applicants' previously filed response). Accordingly, the rejection appears to be in order for withdrawal.

Claims 19 and 20 were rejected under 35 USC 103(a) as allegedly being unpatentable based on Nakahara in view of Kievits and, further, in view of US4582789 (Sheldon III). Reconsideration is requested in view of the instant amendment taken in conjunction with the corresponding remarks, as follows.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

The totality of each reference's teachings must be considered when combining those teachings with the rest of the prior art. *W. L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

It is impermissible within the framework of §103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

*In re Hedges*, 228 USPQ 685, 687 (Fed. Cir. 1986). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the

applicant." *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). References taken in combination teach away when the combination would produce a "seemingly inoperative device." *In re Sponnoble*, 160 USPQ 237, 244 (CCPA 1969). A "reference teaches away if it leaves the impression that the product would not have the property sought by the applicant." 31 USPQ2d at 1132, citing with approval *In re Caldwell*, 138 USPQ 243, 245 (CCPA 1963). An allegation of obviousness is effectively by showing that the reference teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471 (Fed. Cir. 1997).

As explained, above, present (amended) claim 19 contains the subject matter of claim 15 and—as implicitly acknowledged in the Office Action—the subject matter of claim 15 is patentable over the combined teachings of Nakahara and Kievitz; i.e., claim 15 was not included in the §103(a) rejection based on the combined teachings of Nakahara and Kievitz. Furthermore, Sheldon III neither teaches nor suggests the subject matter of claim 15—now incorporated into claim 11—i.e., the added limitations to

the method being performed in the presence of (i) tris-HCl buffer having a pH of 8.5-8.9 at a final concentration of 50 mM to 80 mM and (ii) magnesium chloride at a final concentration of 12 mM to 20 mM.

Since neither Nakahara nor Kievitz nor Sheldon III, taken alone or together, supports the subject matter of claim 15—to which claim 11 is, now, limited, the rejection as applied to (amended) claim 11 is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008.

Furthermore, in accordance with the presently claimed method, RNA amplification occurs in the presence of, i.a., "inosine triphosphate [ITP] at a final concentration of 3.2 mM to 4.4 mM."

On the other hand, Kievitz teaches an optimum ITP concentration of 2.5 mM for RNA amplification, i.e., according to Kievits (column 3, lines 27-30 and lines 36-37),

Good results are obtained when no more than 50% of the GTP present in an amplification reaction mixture is substituted with ITP. . . . The optimal ratio of ITP:GTP has been found to be approximately 1:3.

Moreover, Nakahara (page 1854, right column, lines 6-9) teaches "The optimal ITP concentration was determined to be 2 mM" for RNA amplification. Sheldon III adds nothing that would have cured the fatal deficiency in each of Keivits and Nakahara, i.e., the failure of either reference to meet the aforesaid limitation—the 3.2 mM to 4.4 mM ITP concentration—on the present claims.

Since neither Nakahara nor Kievitz nor Sheldon iii, taken alone or together, supports the limitation on the present claims to RNA amplification performed in the presence of "inosine triphosphate at a final concentration of 3.2 mM to 4.4 mM," rendering the rejection "inadequate on its face." *Thrift*, 63 USPQ2d at 2008. Accordingly, withdrawal of the rejection under §103(a) based on the combined teachings of Nakahara, Kievits, and Sheldon III, further, appears to be in order.

Claims 13-16 and 19-22 were rejected under 35 USC 103(a) as allegedly being unpatentable based on *Nucleic Acids Research*, 26 (1998), 2150-55 (Leone) in view of *Methods in Molecular Biology*, 38 (1994), 253-60 (Malek). Reconsideration is requested in view of the instant amendment taken in conjunction with the corresponding remarks, as follows.

The method of claim 11, as currently amended, is limited to "being performed in the presence of (i) tris-HCL buffer . . . at a final concentration of 50 mM to 80 mM." Neither Leone nor Malek, taken alone or together, supports the aforesaid limitation on claim 11, i.e., performing the method

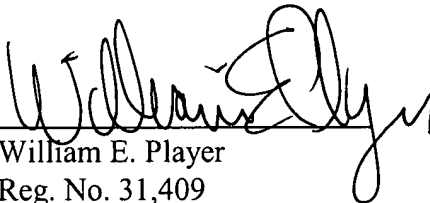
in the presence of "50 mM to 80 mM" (final concentration) tris-HCL buffer, rendering the rejection — applied against claim 11 (amended) — "inadequate on its face." *Thrift* 63 USPQ2d at 2008. As such, withdrawal of the rejection under §103 (a) based on the combined teachings of Leone and Malik appears to be in order.

Favorable action is requested.

Respectfully submitted,

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